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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,135	03/04/2002	Te Piao King	2313/1H587-US1	5158

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EXAMINER	
NOLAN, PATRICK J	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,135	KING ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *20-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-35 are pending.

2. Applicant's election without traverse of Group I, claims 1-19 in the reply filed on 11-4-04 is acknowledged.

Upon further consideration by the Examiner, the species requirement has been removed.

Claims 20-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11-4-04.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The recitation of the specific peptide epitope sequence length in claims 6-9 was not found.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "variant peptide" in line 1. There is insufficient antecedent basis for this limitation in the claim.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptide epitope sequence that is at least 18 amino acids in length, does

not reasonably provide enablement for a peptide epitope sequence that is less than 18 amino acids in length. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The purpose of applicant's claimed peptides are to induce a Th1 type immune response by causing IgG antibodies and stimulation of Th1 T cells. However King et al., (Reference 3 on the IDS submitted 10-15-03) clearly teaches that hybrid proteins with 20-30 amino residues in the peptide epitope sequence have maximal reduction in allergenicity while still retaining adequate immunogenecity. In addition the specification discloses on page 56, Table 3B, that a hybrid protein with only 8 amino acids in the peptide epitope sequence resulted in no IgG antibody response. Lastly Patent Application publication US 2004/0171116 A1 teaches that "insertion of a peptide fragment from an insect allergen into an insect scaffold will in many cases lead to destabilization of the three-dimensional structure of the molecule. Unstable molecules are not suitable for use in vaccination. Secondly, as epitopes almost never consist of a single linear peptide fragment, this approach is not suitable for "grafting" three dimensional epitopes from allergens to scaffold proteins." Since Applicant's working examples demonstrating immunogenecity are limited to peptides of greater than 18 amino acids in length in the peptide epitope sequence and the prior art recognizes that size of the epitope does matter in regards to immunogenecity and that even if a linear peptide is administered is does not always lead to an antibody immune response due to the fact that not all epitopes are linear, it would require an undue amount of experimentation to practice the breadth of Applicant's claimed invention as currently recited.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Monsalve et al., (Reference 1 on the IDS submitted 10-15-03) or Monsalve et al., (Reference 7 on the IDS submitted 10-15-03) as evidenced by King et al. (Reference 3, on the IDS submitted 10-15-03).

Both Monsalve et al., references teach the same hybrid construct, PV 156-204, which contains the terminal 49 amino acids (SEQ ID NO. 8 in claim, which contains both a loop and corner region) of Ves Ag5 in a scaffold protein of Pol a 5, that is 59% identical to Ves Ag5. Furthermore, the references teach decreased allergenicity but retaining immunogenecity and King et al., which generates the same construct in Yeast, as do both Monsalves et al., references, with a EAEAEF signal peptide that cause the hybrid to be secreted with a protease cleavage site encompassed within the signal peptide, as evidenced by King et al., on page 6061. Claim 6 is included because 49 amino acids reasonable reads upon about 45 amino acids.

The prior art teachings anticipate the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monsalve et al., (Reference 1 on the IDS submitted 10-15-03) or Monsalve et al., (Reference 7 on the IDS submitted 10-15-03) as evidenced by King et al. (Reference 3, on the IDS submitted 10-15-03) in view of US Patent 6,639,054 B1.

Mosalve et al., Monsalve et al., and King et al., have been discussed supra.

The claimed invention differs from the prior art teachings by the recitation of a conservative amino acid change in the peptide epitope sequence. However the '054 patent specifically teaches that a conservative substitution of an amino acid is known to reduce IgE binding of known epitopes.

Therefore one of ordinary skill in the art would have been motivated to a make a conservative substitution in the peptide epitope sequence of the hybrid protein taught by Monsalve et al., or Monsalve et al., because said conservative substitution is known to reduce IgE binding of known epitopes and both Monsalve et al., references teach it is desirable to decrease IgE reactivity, i.e. allergenicity, of their hybrid molecules for potential therapeutic uses in treating allergy.

11. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
January 25, 2005